**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | ) | MDL NO. 1456 |
| | ) | CIVIL ACTION NO. 01-12257-PBS |
| | ) | SUBCATEGORY NO. 08-11200-PBS |
| THIS DOCUMENT RELATES TO: | ) | |
| UNITED STATES ex rel. LINNETTE SUN and GREG HAMILTON, RELATORS v. BAXTER HEALTHCARE CORPORATION | ) | |

**MEMORANDUM AND ORDER**

January 26, 2012

Saris, U.S.D.J.

## I. INTRODUCTION

In this qui tam action, Baxter Healthcare Corporation ("Baxter") has moved for partial summary judgment with respect to federal False Claims Act[1] claims involving its pricing of hemophilia blood clotting therapies Recombinate and Advate. Baxter argues, among other things, that these claims are barred by the Settlement Agreement and Release executed by Baxter, and

[1] The remaining counts relate to relator Linnette Sun's retaliation and employment discrimination claims.

an earlier relator Ven-A-Care of the Florida Keys, Inc., ("Ven-A-Care") which was consented to by the government. After hearing, Baxter's Motion for Partial Summary Judgment (Docket No. 135) is **ALLOWED**.

## II. BACKGROUND

This decade-long, nationwide multi-district litigation involves the pricing of pharmaceutical drugs reimbursed by Medicare, Medicaid, private insurers, and patients making coinsurance payments based on average wholesale price ("AWP") between 1991 and 2005. The Court assumes familiarity with AWP drug pricing discussed in this case and the related multi-district litigation. See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., No. 01-12257-PBS, 2010 WL 1375298 (D. Mass. Mar. 25, 2010); In re Pharm. Indus. Average Wholesale Price Litig., 491 F.Supp. 2d 20 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009).

Relators Linnette Sun and Greg Hamilton claim Baxter inflated the prices of drugs and biologics, including Recombinate and Advate, and caused overpayments by Medicaid and Medicare. The Court has already dismissed Count I (submitting false claims in violation of the federal False Claims Act) as to all drugs other than Advate and Recombinate, Count II (violations of the federal

False Claims Act through violations of the Stark Act), Count III (violations of the federal False Claims Act through Best Prices violations), and Counts VII-XXI (violation of various state false claims acts).

Sun and Hamilton arrived late to the AWP table. In 1995, *qui tam* relator Ven-A-Care filed under seal its complaint alleging various drug companies, including Baxter, inflated the prices of many drugs, including Recombinate, to cause overpayments by Medicaid and Medicare. Ten years later, Relators Sun and Hamilton filed their complaint, which also alleged that Baxter inflated drug prices to cause overpayments by Medicaid and Medicare. The Ven-A-Care complaint was later unsealed in 2010.

On October 5, 2011, Baxter and Ven-A-Care executed a Settlement Agreement and Release. It "fully and finally releases, acquits, and forever discharges" Baxter from any "claim, action, suit, demand, right, cause of action, liability, judgment, damage, or proceeding . . . which has been asserted, could have been asserted, or could be asserted in the future . . . for or arising from any of the Covered Conduct . . . ." Settlement Agreement and Release at ¶ III.7, Civil Action No. 1:01-cv-12257-PBS (Oct. 7, 2011) (Master Doc. No. 7832-1). The agreement defines the term "Covered Conduct" as

"the conduct described in Subparagraph II.E. of this Agreement and any action, omission, or other conduct alleged in any of the Civil Actions . . . ." Id. at ¶ II.F. Subparagraph II.E. describes Baxter's submission of false claims to Medicaid and Medicare and its reporting of false prices for "any and all drugs manufactured, marketed and/or sold by or on behalf of any Baxter Party . . . including, without limitation, Baxter Covered Drugs with Labeler Codes 00338 and 00944 and the drug Claforan marketed under Labeler Code 00039 (the 'Baxter Covered Drugs')." Id. at ¶ II.E. It is undisputed that Recombinate and Advate fall under Labeler Code 00944.

The United States (and the state of Florida) consented to the dismissal with prejudice of Ven-A-Care's claims. The United States provided its written consent pursuant to 31 U.S.C. § 3730(b)(1), which agreed to dismissal with prejudice of the claims in the action "pursuant to, and as limited by, the Settlement Agreement and Release." The written consent concludes, "that the amount of $25,000,000 that it will receive in connection with the settlement is fair, adequate, and reasonable as to the United States under all the circumstances."[2] With this

[2] Consent of the United States of America to the Relator's Dismissal with Prejudice of Claims Pursuant to 31 U.S.C. § 3730(b)(1), Civil Action No. 1:01-cv-12257-PBS (Oct. 7, 2011) (Master Doc. No. 7831-1).

consent, on October 17, 2011, the court allowed a proposed Order of Dismissal with Prejudice that noted "the United States' Consent" and "the lack of objection to the proposed Settlement."[3] The $25 million has been transferred to the U.S. Treasury.

## III. DISCUSSION

### A. Standard of Review

Summary judgment is appropriate when "'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" Barbour v. Dynamics Research Corp., 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). To succeed on a motion for summary judgment, "the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990).

Once the moving party has made such a showing, the burden shifts to the non-moving party, who "may not rest on mere allegations or denials of his pleading, but must set forth

[3] Order of Dismissal with Prejudice of Certain Claims Against Baxter Defendants, Civil Action No. 1:01-cv-12257-PBS (Oct. 7, 2011) (Master Doc. No. 7832-2).

specific facts showing there is a genuine issue for trial." Barbour, 63 F.3d at 37 (internal quotations omitted). The non-moving party must establish that there is "sufficient evidence favoring [its position] for a jury to return a verdict [in its favor]. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249-50 (1986)(internal citations omitted). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36 (citation omitted).

**B. Settlement Agreement and Release**

Under the federal False Claims Act, a person may bring an action "in the name of the Government" seeking civil remedies for fraud against the United States. 31 U.S.C. § 3730(b)(1). "The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." Id. Thus, the government has "an absolute veto power over voluntary settlements in *qui tam* False Claims Act suits." Searcy v. Philips Elecs. N. Am. Corp., 117 F.3d 154, 158 (5th Cir. 1997); accord United States v. Health Possibilities,

P.S.C., 207 F.3d 335, 339 (6th Cir. 2000). This veto power is necessary because

> relators can manipulate settlements in ways that unfairly enrich them and reduce benefits to the government . . . . In *qui tam* litigation, [] there is a danger that a relator can boost the value of settlement by bargaining away claims on behalf of the United States . . . . If the government decides the settlement isn't worth the cost, § 3730(b)(1) allows the government to resist these tactics and protect its ability to prosecute matters in the future.

Searcy, 117 F.3d at 160. Without this veto power, the public relator would "retain sole authority to broadly bargain away government claims." Health Possibilities, 207 F.3d at 340. The government may veto a settlement agreement that it believes provides too broad a release by refusing to consent pursuant 31 U.S.C. § 3730(b)(1).

Baxter argues that the claims by the second relators Sun and Hamilton regarding Recombinate and Advate are barred by the Settlement Agreement and Release because the government failed to object to the broad release, as it could have. In similar circumstances, courts have held that the claims of the second relator are extinguished. See San Francisco Technology, Inc. v. Graphic Packaging Intern., Inc., 2011 WL 2909275, *1, *5 (N.D. Ga. June 16, 2011) (where one *qui tam* relator's settlement with defendant of claims brought under federal false marking statute,

35 U.S.C. § 292, included a broad release "from and for any and all claims . . . which were or could have been alleged in the Litigation" and was approved by the United States, the court determined that "[b]y failing to object to the language of the settlement agreement, the government has, in effect, revoked the partial assignment of its claim to [a second relator]" and thus the settlement agreement barred the second relator's claims); Simonian v. Irwin Indus. Toll Co., 2011 WL 147717, *6 (N.D. Ill. Jan. 18, 2011) (*qui tam* relator's settlement with defendant of claims brought under federal false marking statute reached pursuant to a "broad general release[] encompass[ing] both known and unknown claims" extinguished another relator's claims).

Sun and Hamilton argue that because the government consented only to the dismissal of Ven-A-Care's claims, and because Ven-A-Care's claims do not cover Advate, their Advate claim may proceed. At the November 8, 2011, motion hearing, this Court asked whether "the Department of Justice would like to be heard on this issue of what the consent [it filed in October] means." Mot. Hr'g Tr. at 29. In response, the government stated in a two-sentence filing that its consent filed on October 7, 2011, reflected the United States' "consent to the dismissal with

prejudice only of claims pled in relator Ven-A-Care's complaint against Baxter Healthcare Corporation and Baxter International, Inc."[4]

Sun and Hamilton argue the United States never actually consented to a release of claims for Advate, because the reference to "Labeler Code 00944" in the settlement agreement must be read as "Labeler Code 00944 drugs identified in the Ven-A-Care complaint." The terms of the settlement agreement should be construed by applying "the same basic rules that govern the interpretation of ordinary contracts" such that "terms within [the] contract are accorded their 'plain, ordinary, and natural meaning.'" Nault v. United States, 517 F.3d 2, 4 (1st Cir 2008) (internal citations omitted). The language of the Settlement Agreement and Release covers "*any and all* drugs manufactured, marketed and/or sold by or on behalf of any Baxter Party . . . including, *without limitation*, Baxter Covered Drugs with Labeler Codes 00338 and 00944 . . . ." Settlement Agreement and Release at ¶ II.E, Docket No. 7832-1 (emphasis added). It also covers

[4] Statement of the Untied States Regarding the Consent of the United States to the Dismissal with Prejudice of Claims Pursuant to 31 U.S.C. § 3730(b)(1) in a Related Matter, Civil Action No. 1:01-cv-12257-PBS (Nov. 14, 2011) (Master Doc. No. 7897).

claims that "could have been asserted, or could be asserted in the future." Id. at ¶ III.7. In light of these provisions, the plain language of the Settlement and Release indicates it is not limited to drugs identified in the Ven-A-Care complaint.

The relators argue that a narrow interpretation of this release as limited only to the claims in the complaint is consistent with the requirements of the False Claims Act and public policy. Yet the False Claims Act does not require such an interpretation. Courts regularly sanction broad releases contained within settlement agreements in *qui tam* and other cases. See, e.g., In re Gen. Am. Life Ins. Co. Sales Practices Litig., 357 F.3d 800, 805 (8th Cir. 2004) ("There is no impropriety in including in a settlement a description of claims that is somewhat broader than those that have been specifically pleaded. In fact, most settling defendants insist on this."); San Francisco Technology, 2011 WL 2909275 at *3 ("Eaglewood argues that the settlement agreement is too broad . . . . [but n]othing in this result is inequitable . . . . the False Claims Act contains several safeguards not found in [the false marking statute] for protecting the government's interests . . . ."); Simonian, 2011 WL 147717 at *5 ("It is common for parties to

settle contested litigation with broad releases of the type used in the[se] cases, which relinquished improper marking claims whether known or unknown, and whether or not asserted in the lawsuits. We see nothing in [the false marking statute] that alters this basic tenet of contract law.").

To address this issue of overly broad releases that give away everything but the kitchen sink, the False Claims Act permits the government to withhold its consent to a settlement pursuant to 31 U.S.C. § 3730(b)(1) if it believes the settlement provides too expansive a release to the defendant. See United States v. Health Possibilities, P.S.C., 207 F.3d 335, 340 (6th Cir. 2000); Searcy v. Philips Elecs. N. Am. Corp., 117 F.3d 154, 160 (5th Cir. 1997). In fact, the United States did just that when it objected before this court to a proposed settlement of another case that is part of this same multi-district AWP litigation on the basis that the settlement released claims in connection with additional drugs the government had not fully investigated.[5]

[5] See United States' Memorandum in Support of Its Opposition to the Motion to Approve the Proposed Settlement Between Schering-Plough Corporation, Warrick Pharmaceuticals Corporation, California, Florida and Relator Ven-A-Care of the Florida Keys at 10-15, Civil Action No. 1:01-cv-12257-PBS, Subcategory No. 06-

Plaintiffs next suggest that Baxter and Ven-A-Care surreptitiously agreed to sneak language into the settlement in order to vitiate this case. But the government does not contend it was "hoodwinked" by any intentional or negligent misrepresentations as to the scope of the claims to be released. To be sure, there may be situations where the government misunderstands the fine print of hyper-technical lawyer wordsmithing, which obfuscates rather than clarifies, but this is longstanding litigation with which the government has extensive familiarity. Multiple government lawyers were involved. In light of the complexity and expense of the litigation, it would have been quite predictable that Baxter would seek to cut off all future liability to the federal government for its practices of inflating AWP pricing. Why else would Baxter settle? In any event, the government in its terse filing does not now object to the settlement or assert a misunderstanding as to the scope of the release. In light of the undisputed record, Baxter is entitled to judgment as a matter of law.

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11337 (Aug. 28, 2009) (Master Doc. No. 6414, Subcategory Doc. No. 392).

## IV. ORDER

The Court **ALLOWS** defendant's motion for partial summary judgment with respect to the remaining federal False Claims Act claims related to Recombinate and Advate (Docket No. 135). The parties shall submit a status report within 14 days as to the remaining claims.

/s/ PATTI B. SARIS
PATTI B. SARIS
UNITED STATES DISTRICT JUDGE